

Amir M. Nassihi (SBN: 235936)  
anassihi@shb.com  
SHOOK, HARDY & BACON L.L.P.  
555 Mission Street Suite 2300  
San Francisco, California 94105  
Telephone: (415) 544-1900  
Facsimile: (415) 391-0281

Michael L. Mallow (SBN: 188745)  
mmallow@shb.com  
Mayela C. Montenegro-Urch (SBN: 304471)  
mmontenegro@shb.com  
SHOOK, HARDY & BACON L.L.P.  
2049 Century Park East, Suite 3000  
Los Angeles, California 90067  
Telephone: (424) 285-8330  
Facsimile: (424) 204-9093

*[Additional Counsel on Signature Page]*

Attorneys for Defendants  
INTERNATIONAL MEDICAL DEVICES, INC.,  
MENOVA INTERNATIONAL, INC., GESIVA  
MEDICAL, LLC, JAMES J. ELIST, M.D., A  
MEDICAL CORPORATION, and DR. JAMES ELIST  
Attorneys for Defendants  
INTERNATIONAL

UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA – EASTERN DIVISION

EDWARD PEÑA, individually and on behalf of others similarly situated,

Plaintiff,

V.

INTERNATIONAL MEDICAL  
DEVICES, INC., MENOVA  
INTERNATIONAL, INC., GESIVA  
MEDICAL, LLC, JAMES J. ELIST M.  
D., a Medical Corporation, and Dr. James  
ELIST

Defendants.

Case No. 2:22-cv-03391-SSS (PLAx)

Judge: Hon. Sunshine S. Sykes

# DEFENDANTS' ANSWER TO PLAINTIFF'S SECOND AMENDED CLASS ACTION COMPLAINT

Complaint Filed: May 25, 2022  
First Am. Compl. Filed: June 15, 2022  
Second Am. Compl. Filed: Jan. 20, 2023

1 Defendants International Medical Devices, Inc., Menova International, Inc.,  
 2 Gesiva Medical, LLC, James J. Elist M.D., A Medical Corporation, and Dr. James  
 3 Elist (collectively, “Defendants”), by and through their undersigned counsel, hereby  
 4 answer Plaintiff Edward Peña’s Second Amended Class Action Complaint (“SAC”).

5 The numbered paragraphs below correspond with the numbered paragraphs in  
 6 the SAC. Any allegation in the SAC that has not been expressly admitted is denied.

## 7 I. INTRODUCTION

8 1. Defendants deny the allegations of Paragraph 1.

9 2. Defendants admit that Dr. James J. Elist developed a surgical procedure  
 10 for implanting the Penuma device. They admit that he has performed thousands of  
 11 these procedures, handling patient consults at his clinic in Beverly Hills and  
 12 performing penile implant surgeries in an operating room at the Beverly Hills South  
 13 Pacific Surgery Center. Defendants deny the remaining allegations in Paragraph 2.

14 3. Defendants admit that the website [www.penuma.com](http://www.penuma.com) states that the  
 15 Penuma is “the first FDA-cleared penile implant for cosmetic [male] enhancement.”  
 16 Defendants deny the remaining allegations of Paragraph 3.

17 4. Defendants admit that Plaintiff brings this action, but deny that he is  
 18 entitled to any relief. Defendants deny the remaining allegations of Paragraph 4.

## 19 II. PARTIES

20 5. Defendants are without sufficient information to admit or deny the  
 21 allegations of Paragraph 5. To the extent a further response is required, Defendants  
 22 deny the allegations of Paragraph 5.

23 6. Defendants deny that IMD is located at 717 N. Maple Dr., Beverly Hills,  
 24 CA 90210. Defendants admit the remaining allegations of Paragraph 6.

25 7. Defendants admit the allegations of Paragraph 7.

26 8. Defendants admit the allegations of Paragraph 8.

27 9. Defendants admit the allegations of Paragraph 9.

28 10. Defendants admit the allegations of Paragraph 10.

**III. JURISDICTION AND VENUE**

11. The allegations of Paragraph 11 consist of argument and legal conclusions to which no response is required. To the extent a further response is required, Defendants deny the allegations of Paragraph 11.

12. The allegations of Paragraph 12 consist of argument and legal conclusions to which no response is required. To the extent a response is required, Defendants admit the allegations of Paragraph 12.

13. The allegations of Paragraph 13 consist of argument and legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 13.

14. The allegations of Paragraph 14 consist of argument and legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 14.

15. The allegations of Paragraph 15 consist of argument and legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 15.

**IV. JOINT ENTERPRISE LIABILITY**

16. Defendants deny the allegations of Paragraph 16.

17. Defendants deny the allegations of Paragraph 17.

18. Defendants deny the allegations of Paragraph 18.

19. The allegations of Paragraph 19 consist of argument and legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 19.

20. Defendants deny the allegations of Paragraph 20.

**V. STATEMENT OF FACTS**

21. Defendants are without sufficient information to admit or deny the allegations of Paragraph 21. To the extent a further response is required, Defendants deny the allegations of Paragraph 21.

1           22. Defendants are without sufficient information to admit or deny the  
2 allegations of Paragraph 22. To the extent a further response is required, Defendants  
3 deny the allegations of Paragraph 22.

4           23. Defendants are without sufficient information to admit or deny the  
5 allegations of Paragraph 23. To the extent a further response is required, Defendants  
6 deny the allegations of Paragraph 23.

7           24. Defendants are without sufficient information to admit or deny the  
8 allegations of Paragraph 24. To the extent a further response is required, Defendants  
9 deny the allegations of Paragraph 24.

10          25. Defendants are without sufficient information to admit or deny the  
11 allegations of Paragraph 25. To the extent a further response is required, Defendants  
12 deny the allegations of Paragraph 25.

13          26. Defendants admit that Dr. Elist consulted with Mr. Peña in October 2020,  
14 but deny that this was the first contact Mr. Peña had with Dr. Elist's office.  
15 Defendants admit that Mr. Pena filled out an eligibility questionnaire in June 2020 and  
16 that Mr. Peña met with other employees of James J. Elist MD, a Medical Corporation.  
17 Defendants admit that Dr. Elist performed surgery to implant the Penuma device in  
18 Mr. Peña's body. Defendants deny the remaining allegations of Paragraph 26.

19          27. Defendants deny the allegations of Paragraph 27.

20          28. Defendants are without sufficient information to admit or deny the  
21 allegations of Paragraph 28. To the extent a further response is required, Defendants  
22 deny the allegations of Paragraph 28.

23          29. Defendants are without sufficient information to admit or deny the  
24 allegations of Paragraph 29. To the extent a further response is required, Defendants  
25 deny the allegations of Paragraph 29.

26          30. Defendants are without sufficient information to admit or deny the  
27 allegations of Paragraph 30. To the extent a further response is required, Defendants  
28 deny the allegations of Paragraph 30.

**VI. CLASS ALLEGATIONS**

31. Defendants admit Dr. Elist has received numerous patents related to the Penuma device. Defendants deny the remaining allegations of Paragraph 31.

32. Defendant deny the allegations of Paragraph 32.

33. Defendants admit that Dr. Elist is the sole owner and has served as the president of IMD. Defendants further admit that Jonathan Elist is IMD's chief executive officer. Defendants deny the remaining allegations of Paragraph 33.

34. Defendants admit the allegations of Paragraph 34.

35. Defendants admit that Dr. Elist trains urologists to implant the Penuma. Defendants deny the remaining allegations of Paragraph 35.

36. Defendants state that the article and blog posting discussed in Paragraph 36 speak for themselves, and Defendants deny Plaintiff's characterization of them. The remaining allegations of Paragraph 36 consist of argument to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 36.

37. Defendants admit the study from 2018, entitled "A Single-Surgeon Retrospective and Preliminary Evaluation of the Safety and Effectiveness of the Penuma Silicone Sleeve Implant for Elective Cosmetic Correction of the Flaccid Penis," was conducted and published in a peer-reviewed journal. That study and others discussed in Paragraph 37 speak for themselves, and Defendants deny Plaintiffs' characterization of them. The remaining allegations of Paragraph 37 consist of arguments to which no response is required. To the extent a further response is required, Defendants deny the allegations of Paragraph 37.

38. Defendants admit the Penuma device is a medical device that is subject to the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). The remaining allegations of Paragraph 38 consist of argument and legal conclusion to which no response is required. To the extent a further response is required, Defendants deny the allegations of Paragraph 38.

1           39. The allegations of Paragraph 39 consist of argument and legal conclusion  
2 to which no response is required. To the extent a response is required, Defendants  
3 deny the allegations of Paragraph 39.

4           40. The allegations of Paragraph 40 consist of argument and legal conclusion  
5 to which no response is required. To the extent a response is required, Defendants  
6 deny the allegations of Paragraph 40.

7           41. The allegations of Paragraph 41 consist of argument and legal conclusion  
8 to which no response is required. To the extent a response is required, Defendants  
9 deny the allegations of Paragraph 41.

10          42. Defendants admit that National Medical Devices sought FDA clearance  
11 to market the Penuma on or about September 1, 2004 and that the FDA granted 510(k)  
12 clearance on October 24, 2004. National Medical Devices' submission and FDA's  
13 clearance speak for themselves. The remaining allegations of Paragraph 42 consist of  
14 argument and legal conclusion to which no response is required. To the extent a  
15 response is required, Defendants deny the allegations of Paragraph 42.

16          43. Defendants admit that IMD submitted a 510(k) premarket notifications  
17 on December 20, 2016, and December 19, 2018, which FDA granted on February 1,  
18 2017, and January 23, 2019. IMD's submissions and FDA's clearances speak for  
19 themselves, and Defendants deny Plaintiff's characterization of them and deny that  
20 this paragraph describes all FDA clearances obtained by IMD. The remaining  
21 allegations consist argument to which no response is required. To the extent a  
22 response is required, Defendants deny the remaining allegations of Paragraph 43.

23          44. Defendants deny the allegations of Paragraph 44.

24          45. The allegations of Paragraph 45 consist of arguments to which no  
25 response is required. To the extent a response is required, Defendants deny the  
26 allegations of Paragraph 45.

27          46. Defendants specifically deny Plaintiffs' allegation that the Penuma is  
28 "neither safe and effective nor FDA-cleared." The remaining allegations of Paragraph

1 46 consist of argument to which no response is required. To the extent a response is  
2 required, Defendants deny the allegations of Paragraph 46.

3 47. Defendants deny the allegations of Paragraph 47.

4 48. Defendants admit that the Penuma device is marketed on  
5 [www.drelist.com](http://www.drelist.com) by Defendant James J. Elist, MD, a Medical Corporation and on  
6 [www.penuma.com](http://www.penuma.com) by Defendant International Medical Devices, Inc. The websites  
7 speak for themselves, and Defendants deny Plaintiff's characterization of them.  
8 Defendants deny the remaining allegations of Paragraph 48.

9 49. Defendants admit that the Penuma is marketed by Defendant James J.  
10 Elist, MD, a Medical Corporation on [www.drelist.com](http://www.drelist.com). The website speaks for itself,  
11 and Defendants deny Plaintiff's characterization of it. Defendants deny the remaining  
12 allegations of Paragraph 49.

13 50. Defendants deny the allegations of Paragraph 50.

14 51. Defendants deny the allegations of Paragraph 51.

15 52. Defendants deny the allegations of Paragraph 52.

16 53. Defendants deny the allegations of Paragraph 53.

17 54. Defendants deny the allegations of Paragraph 54.

18 55. Defendants deny the allegations of Paragraph 55.

19 56. Defendants deny the allegations of Paragraph 56.

20 57. Defendants deny the allegations of Paragraph 57.

21 58. Defendants deny the allegations of Paragraph 58.

22 59. Defendants deny the allegations of Paragraph 59.

23 60. Defendants deny Plaintiff's allegations related to the cost of the Penuma  
24 device and implantation surgery, the amount paid to IMD, and that "all defendants  
25 profit . . . from the sales of the Penuma device." The remaining allegations of  
26 Paragraph 60 consist of argument to which no response is required. To the extent a  
27 response is required, Defendants deny the allegations of Paragraph 60.

28 61. Defendants admit Dr. Elist has performed thousands of Penuma



1 implantation procedures. Defendants deny the remaining allegations of Paragraph 61.

2 62. Defendants deny the allegations of Paragraph 62.

3 63. Defendants deny the allegations of Paragraph 63.

4 64. Defendants deny the allegations of Paragraph 64.

5 65. Defendants state that the studies cited in Paragraph 65 speak for  
6 themselves, and Defendants deny Plaintiff's characterization of them. Defendants  
7 deny the remaining allegations of Paragraph 65.

8 66. Defendants state that the website and study cited in paragraph 66 speak  
9 for themselves, and Defendants deny Plaintiff's characterization of them. Defendants  
10 deny the remaining allegations of Paragraph 66.

11 67. Defendants deny the allegations of Paragraph 67.

12 68. Defendants deny the allegations of Paragraph 68.

13 69. Defendants deny the allegations of Paragraph 69.

14 70. Defendants deny the allegations of Paragraph 70.

15 *[Paragraph Under Heading "D. Class Definition" is Missing in SAC]*

16 The allegations of this Paragraph consist of argument and legal conclusion to  
17 which no response is required. To the extent a response is required, Defendants deny  
18 the allegations of this Paragraph.

19 71. The allegations of Paragraph 71 consist of argument and legal conclusion  
20 to which no response is required. To the extent a response is required, Defendants  
21 deny the allegations of Paragraph 71.

22 72. The allegations of Paragraph 72 consist of argument and legal conclusion  
23 to which no response is required. To the extent a response is required, Defendants  
24 deny the allegations of Paragraph 72.

25 73. The allegations of Paragraph 73 consist of argument and legal conclusion  
26 to which no response is required. To the extent a response is required, Defendants  
27 deny the allegations of Paragraph 73.

28 74. The allegations of Paragraph 74 consist of argument and legal conclusion



1 to which no response is required. To the extent a response is required, Defendants  
2 deny the allegations of Paragraph 74.

3 75. The allegations of Paragraph 75 consist of argument and legal conclusion  
4 to which no response is required. To the extent a response is required, Defendants  
5 deny the allegations of Paragraph 75, including the subparts.

6 76. The allegations of Paragraph 76 consist of argument and legal conclusion  
7 to which no response is required. To the extent a response is required, Defendants  
8 deny the allegations of Paragraph 76.

9 77. The allegations of Paragraph 77 consist of argument and legal conclusion  
10 to which no response is required. To the extent a response is required, Defendants  
11 deny the allegations of Paragraph 77.

## 12 VII. CLAIMS

### 13 COUNT ONE – Violation of California’s False Advertising Law, CAL. BUS. & 14 PROF. CODE § 17500 (“FAL”)

15 78. Defendants incorporate their preceding responses by reference.

16 79. The allegations of Paragraph 79 consist of argument and legal conclusion  
17 to which no response is required. To the extent a response is required, Defendants  
18 deny the allegations of Paragraph 79.

19 80. The allegations of Paragraph 80 consist of argument and legal conclusion  
20 to which no response is required. To the extent a response is required, Defendants  
21 deny the allegations of Paragraph 80.

22 81. The allegations of Paragraph 81 consist of argument and legal conclusion  
23 to which no response is required. To the extent a response is required, Defendants  
24 deny the allegations of Paragraph 81.

25 82. Defendants deny the allegations of Paragraph 82.

26 83. Defendants deny the allegations of Paragraph 83.

27 84. Defendants deny the allegations of Paragraph 84.

28 85. Defendants deny the allegations of Paragraph 85.

1 86. Defendants deny the allegations of Paragraph 86.

2 87. Defendants deny the allegations of Paragraph 87.

3 **COUNT TWO – Violation of California’s Consumers Legal Remedies Act, CAL.**

4 **CIV. CODE § 1750 *et seq.* (“CLRA”)**

5 88. Defendants incorporate their preceding responses by reference.

6 89. The allegations of Paragraph 89 consist of argument and legal conclusion  
7 to which no response is required. To the extent a response is required, Defendants  
8 deny the allegations of Paragraph 89.

9 90. The allegations of Paragraph 90 consist of argument and legal conclusion  
10 to which no response is required. To the extent a response is required, Defendants  
11 deny the allegations of Paragraph 90.

12 91. Defendants deny the allegations of Paragraph 91.

13 92. The allegations of Paragraph 92 consist of argument and legal conclusion  
14 to which no response is required. To the extent a response is required, Defendants  
15 deny the allegations of Paragraph 92.

16 93. The allegations of Paragraph 93 consist of argument and legal conclusion  
17 to which no response is required. To the extent a response is required, Defendants  
18 deny the allegations of Paragraph 93.

19 94. Defendants deny the allegations of Paragraph 94, including subparts.

20 95. Defendants deny the allegations of Paragraph 95.

21 96. Defendants deny the allegations of Paragraph 96, including subparts.

22 97. Defendants deny the allegations of Paragraph 97.

23 98. Defendants deny the allegations of Paragraph 98.

24 99. The allegations of Paragraph 99 consist of argument and legal conclusion  
25 to which no response is required. To the extent a response is required, Defendants  
26 deny the allegations of Paragraph 99.

27 100. Defendants deny the allegations of Paragraph 100.

28 101. Defendants deny the allegations of Paragraph 101.

1 102. Defendants deny the allegations of Paragraph 102.

2 103. Defendants deny the allegations of Paragraph 103.

3 104. The allegations of Paragraph 104 consist of argument and legal  
4 conclusion to which no response is required. To the extent a response is required,  
5 Defendants deny the allegations of Paragraph 104.

6 105. The allegations of Paragraph 105 consist of argument and legal  
7 conclusion to which no response is required. To the extent a response is required,  
8 Defendants deny the allegations of Paragraph 105.

9 **COUNT THREE – Violation of California’s Unfair Competition Law, CAL. BUS.**  
10 **& PROF. CODE § 17200 *et seq.* (“UCL”)**

11 106. Defendants incorporate their preceding responses by reference.

12 107. The allegations of Paragraph 107 consist of argument and legal  
13 conclusion to which no response is required. To the extent a response is required,  
14 Defendants deny the allegations of Paragraph 107.

15 108. The allegations of Paragraph 108 consist of argument and legal  
16 conclusion to which no response is required. To the extent a response is required,  
17 Defendants deny the allegations of Paragraph 108.

18 109. Defendants deny the allegations of Paragraph 109.

19 110. Defendants deny the allegations of Paragraph 110, including subparts.

20 111. Defendants deny the allegations of Paragraph 111.

21 112. Defendants deny the allegations of Paragraph 112.

22 113. Defendants deny the allegations of Paragraph 113.

23 114. Defendants deny the allegations of Paragraph 114.

24 115. Defendants deny the allegations of Paragraph 115.

25 116. Defendants deny the allegations of Paragraph 116.

26 117. The allegations of Paragraph 117 consist of argument and legal  
27 conclusion to which no response is required. To the extent a response is required,  
28 Defendants deny the allegations of Paragraph 117.

118. The allegations of Paragraph 118 consist of argument and legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 118.

## **VIII. CONCLUSION AND PRAYER**

Defendants deny each and every allegation in the Conclusion and Prayer.

### **AFFIRMATIVE DEFENSES**

Defendants plead the following affirmative defenses. By such pleading, Defendants intend no alteration of burden of proof or burden of going forward with evidence that otherwise exists with respect to any particular issue at law or in equity. Furthermore, that the defenses are pleaded in the alternative does not constitute an admission of liability as to any claim or cause of action or that Plaintiff is entitled to any relief whatsoever.

#### **FIRST AFFIRMATIVE DEFENSE**

##### **(Failure to State a Claim)**

1. Plaintiff's SAC, and each and every purported cause of action therein, fails to state a claim upon which relief can be granted.

#### **SECOND AFFIRMATIVE DEFENSE**

##### **(Preemption)**

2. Some or all of the claims made in Plaintiff's SAC, including claims made on behalf of the proposed putative class, are barred because they are preempted by federal law and/or regulations.

#### **THIRD AFFIRMATIVE DEFENSE**

##### **(Primary Jurisdiction)**

3. Some or all of the claims made in Plaintiff's SAC, including claims made on behalf of the proposed putative class, may be barred because of the doctrine of primary jurisdiction.

#### **FOURTH AFFIRMATIVE DEFENSE**

##### **(Accord and Satisfaction)**

1           4. If any persons claiming to be members of the proposed class have  
2 resolved similar or the same claims as those alleged in the SAC, they may be barred  
3 from recovery, in whole or in part, on the ground that they are subject to the defense  
4 of accord and satisfaction.

5                                   **FIFTH AFFIRMATIVE DEFENSE**

6                                   **(Statute of Limitations)**

7           5. The claims of Plaintiff and/or members of the proposed class may be  
8 time-barred under the applicable statute of limitations.

9                                   **SIXTH AFFIRMATIVE DEFENSE**

10                                  **(Waiver, Estoppel, and/or Laches)**

11          6. The claims of Plaintiff and/or members of the proposed class are barred,  
12 in whole or in part, based on the doctrines of waiver, estoppel, and/or laches.

13                                  **SEVENTH AFFIRMATIVE DEFENSE**

14                                  **(Failure to Mitigate Damages)**

15          7. The claims of Plaintiff and/or members of the proposed class are barred,  
16 in whole or in part, to the extent Plaintiff and/or members of the proposed class have  
17 failed to mitigate damages and/or have caused some or all of the alleged damage of  
18 which they now complain.

19                                  **EIGHTH AFFIRMATIVE DEFENSE**

20                                  **(Adequate Remedy at Law)**

21          8. The claims of Plaintiff and members of the proposed class for equitable  
22 remedies are barred because Plaintiff and members of the proposed class have an  
23 adequate remedy at law.

24                                  **NINTH AFFIRMATIVE DEFENSE**

25                                  **(Acts of Other Parties)**

26          9. Any and all violations alleged in the SAC were proximately caused or  
27 contributed to by the acts, omissions, or conduct of parties other than Defendants, and  
28 for this reason, the SAC fails to state facts sufficient to constitute a cause of action

1 against Defendants. In the alternative, Defendants are entitled to contribution from  
2 such other parties or proration of civil penalties or other relief.

3 **TENTH AFFIRMATIVE DEFENSE**

4 **(Set Off)**

5 10. To the extent Plaintiff and/or members of the proposed class recoup any  
6 damages, such damages are subject to set off and recoupment.

7 **ELEVENTH AFFIRMATIVE DEFENSE**

8 **(Improper Venue)**

9 11. Plaintiff and/or members of the proposed class are barred from pursuing  
10 their claims within the SAC because venue is improper.

11 **RESERVATION OF RIGHT TO AMEND**

12 Defendants reserve the right to assert additional defenses, counterclaims, cross-  
13 claims, or third-party claims as they become known throughout the course of this  
14 litigation and may become available under the substantive law of the State of  
15 California.

16 WHEREFORE, Defendants ask for the following relief:

- 17 1. For dismissal of Plaintiff's Second Amended Class Action Complaint  
18 with prejudice;  
19 2. For judgment in favor of Defendants against Plaintiff;  
20 3. For the costs of suit herein; and  
21 4. For such other and further relief as the Court may deem just and proper.

22 **DEMAND FOR JURY TRIAL**

23 Defendants hereby demand a trial by jury on all issues so triable.  
24  
25  
26  
27  
28

1 Dated: May 12, 2023

Respectfully submitted,

2 SHOOK, HARDY & BACON L.L.P.

3 By: /s/ Amir M. Nassihi

4 Amir M. Nassihi

5 Michael L. Mallow

Jennifer M. Stevenson

6 Mayela C. Montenegro-Urch

7 Jennifer M. Stevenson (admitted *pro hac*  
8 *vice*)

jstevenson@shb.com

9 SHOOK, HARDY & BACON L.L.P.

2555 Grand Boulevard

10 Kansas City, Missouri 64108

Telephone: (816) 474-6550

11 Facsimile: (816) 421-5547

12 Attorneys for Defendants

13 INTERNATIONAL MEDICAL DEVICES,

14 INC., MENOVA INTERNATIONAL,

INC., GESIVA MEDICAL, LLC, JAMES

15 J. ELIST M.D., a Medical Corporation, and

16 DR. JAMES ELIST